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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,022	02/10/2004	Gregory B. Altshuler	105090-0235	2212
21125 7590 01/22/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER JOHNSON III, HENRY M	
			ART UNIT 3739	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/22/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,022	ALTSHULER ET AL.	
	Examiner	Art Unit	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12 and 14-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-10, 12, 14-16, 18, 21-23, 25-27, 29, 32 and 34-46 is/are rejected.
- 7) ☒ Claim(s) 3, 17, 19, 20, 28, 30 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments filed November 24, 2006 have been fully considered but they are not persuasive.

The term two separate spectral bands can be broadly interpreted as having any bandwidth and overlapping or non-overlapping. The parameters may be arbitrarily determined when using a broadband source. The applicant's specification states several distinct bands in paragraph 0086, but no specific bands are claimed. Further, the applicant states that multiple bands may be alternatively used to "treat the same conditions more effectively or to treat two different conditions", but again no specifics as to any criticality of separate bands or unexpected results. Azar et al. disclose a broadband source with the wavelengths absorbed by oxyhemoglobin excluded, which inherently leaves multiple spectral bands. The blue and UV emitted by limura are clearly different spectrum, notwithstanding the terminology used by limura.

The term phototherapeutic radiation is a relative term in that it is dependent on the intended target of the radiation, therefore based on intended use. Since both Azar et al. and limura are used for cleaning a mouth area, it is inherent they provide phototherapeutic radiation targeted at an endogenous chromophore or a photosensitizer.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the embodiments with

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bristles and bodies conformable to an oral cavity must be shown or the features canceled from the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22 and 34-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

An embodiment with the bristles coupled to fewer than all of the radiating element is not explicitly disclosed and is arguably shown in the drawings. With no criticality or unexpected results associated with this unique arrangement, it would appear to be claimed solely to circumvent prior art cited.

An embodiment with bristles and a body that conforms to an oral cavity is new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-10, 12, 16, 18, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication US 2001/0024777 to Azar et al. Azar et al. discloses a device for oral hygiene that directs light toward the brushing head, the light may be provided by a gas discharge lamp or flash lamp (paragraph 0041), such lamps being well known for producing multi-spectral or broadband light. At least one filter is provided to select the desired wavelength (paragraph 0027). While the

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filter is disclosed as blocking a specific wavelength, it selects other wavelengths by default. The remaining broad spectrum may be interpreted as being split into distinct spectral bands that may or may not overlap. Azar et al. teach a reflecting surface to direct the radiation into the bristles from multiple directions (Fig. 9). It is inherent the bristles are transparent for delivery of the radiation.

Regarding claims 10, 41 and 42, the claim is directed to the intended use of the apparatus.

Claims 1, 14, 16, 18, 32 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,094,767 to Iimura. Iimura teaches a cleaning apparatus including a light source and light transmitting bristles (abstract). The device may be in a toothbrush configuration for dental hygiene (Col. 11, lines 20-30). The light source may emit blue light and UV light (Col. 5, lines 24-26), which are two distinct spectrums separated by the violet wavelengths. Diffusing particles may be used to diffuse the light (Col. 6, lines 40-45) and the surface of the head opposite the bristles is disclosed as reflecting. To provide light to a target, the bristles must be optically coupled to the radiation source.

Regarding claims 16 and 18, the bristles have a shape and deliver radiation. Without a specific shape the claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,094,767 to Iimura as applied to claim 1 above and further in view of U.S. Patent 6,239,442 to Iimura. Iimura '767 is discussed above, but does not teach reflective coating on the bristles. Iimura '442 teaches the same invention as the previous Iimura patent and includes a light reflecting means on the bristles. It would have been obvious to one skilled in the art to coat the bristles as taught by Iimura '442. of the invention of Iimura '767 to further direct the radiation to the target via the bristles.

Claims 21 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,094,767 to Iimura as applied to claim 1 above and further in view of U.S. Patent 6,862,771 to Muller. Iimura is discussed above, but does not teach a detachable head. Muller teaches a toothbrush with a head with bristles and a radiation source in a handle. The location in the handle is disclosed as convenient if the toothbrush is an electrical toothbrush, i.e. having electrical drive means to move the cleaning bristles in a tooth cleaning operation. The electric drive is interpreted as a vibrating mechanism. The radiation is directed in a direction parallel to the bristles

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either between the bristles or through the optically transparent bristles, thus teaching a plurality of emitters (Fig. 6). A reflecting surface directs the radiation to the bristles (Fig. 6, # 17). Along with the radiation source in the handle, a detector is disclosed for sensing reflected radiation. This detector is interpreted as a diagnostic sensor (Col. 2, lines 38-65). The head is disclosed as being detachable (Col. 8, line 55). It would have been obvious to one skilled in the art to use the detachable head and radiation sensor as taught by Muller in the invention of limura as such interchangeable heads are common and well known for oral hygiene devices.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,094,767 to limura as applied to claim 1 above and further in view of U.S. Patent 6,273,884 to Altshuler et al. limura is discussed above, but does not disclose inhibiting radiation when not in contact with tissue. Altshuler et al. teach a tissue treatment apparatus and the concept of total internal reflection. The optical delivery channel is treated to normally have total internal reflection so that light or other radiation entering the channel is reflected internally, however, when lens (output face) is in contact with a patient's skin, the total internal reflection at the skin-contacting surface is broken due to the change of index of refraction at this surface so that light energy is emitted into the patient's skin (Col. 16, lines 25-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the technique of modifying the index of refraction of the light channel as taught by Altshuler et al. in the invention of limura to limit the radiation to the oral cavity as a safety consideration as suggested by Altshuler et al.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,094,767 to Imura as applied to claim 1 above, and further in view of U.S. Patent 5,133,102 to Sakuma. Imura is discussed above, but does not teach the use of a contact sensor. Sakuma discloses an electronic toothbrush with a handle, head and bristles and a circuit that energizes a radiation device when the bristles contact the teeth, thus sensing contact and completing the circuit via the body of the user. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the contact sensor as taught by Sakuma in the device of Imura to activate the device when in the preferred use position, in contact with the oral tissue as suggested by Sakuma.

Claims 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2001/0024777 to Azar et al. as applied to claim 1 above and further in view of U.S. Patent 6,331,111 to Cao. Azar et al. are discussed above, but do not teach heat control of the radiation source. Cao teaches a device for curing light activated materials as commonly found in the dental art (Col. 2, line 9), thereby establishing a size capable of insertion into a mouth. A light source in the handle is disclosed that may produce multiple wavelengths (Col. 5, lines 58-65). The light source is provided with a heat sink within the handle, a heat sink inherently having a thermally conductive element and being located in the handle the handle would inherently conduct some of the heat (Col. 13, lines 1-25). Thus Cao teaches the removal of heat from a radiation source in a handle. It would have been obvious to one skilled in the art to use the heat sinking methodology as taught by Cao in the invention

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of Azar et al. as the control of heat from a radiation source is common to all arts using such sources and a skilled artisan would be motivated to look to such art to control the heat generated.

Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2001/0024777 to Azar et al. as applied to claim 1 above and further in view of U.S. Patent 4,333,197 to Kuris. Azar et al. are discussed above, but do not teach the use of ultrasonics. Kuris teaches a toothbrush including an ultrasonic capability to enhance the cleaning ability of the brush. It would have been obvious to one skilled in the art to include an ultrasonic capability as taught by Kuris in the invention of Azar et al. to complement the germicidal action of the oral hygiene device.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication US 2001/0024777 to Azar et al. as applied to claim 1 above and further in view of U.S. Patent 3,653,778 to Freiling. Azar et al. are discussed above, but do not teach a drug delivery port. Freiling discloses a toothbrush head that includes ports for the dispensing of toothpaste between the bristles (Fig. 3). This port can clearly be used to dispense any agent desired by the user. It would have been obvious to one skilled in the art to include an agent delivery port as taught by Freiling in the invention of Azar et al. to dispense cleaning agents or photocatalysts to the target area.

Allowable Subject Matter

Claim 24 is allowed.

Claims 3, 17, 19, 20, 28 and 30-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

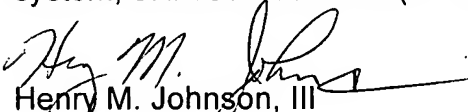
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571)

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272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Henry M. Johnson, III
Primary Examiner
Art Unit 3739